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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------|------------------|
| 10/616,900 | 07/09/2003 | Julie Sudduth-Klinger | 2300-15805CON | 5219 |
| 7590 | 02/16/2006 | | EXAMINER | |
| Chiron Corporation Intellectual Property-R440 P.O. Box 8907 Emeryville, CA 94662-8097 | | | SMITH, CAROLYN L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
| DATE MAILED: 02/16/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/616,900 | SUDDUTH-KLINGER ET AL. | |
| | Examiner | Art Unit | |
| | Carolyn L. Smith | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Detailed Action

This application is a continuation of abandoned application 09/872,850.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method for detecting a cancerous colon cell via probe binding level comparison, classified in class 435, subclass 6.
- II. Claims 6-8, drawn to a method for assessing the cancerous phenotype of a colon cell via expression level comparison, classified in class 702, subclass 19.
- III. Claims 9-12, drawn to a method for suppressing or inhibiting a cancerous phenotype of a cancerous cell, classified in class 435, subclass 325.
- IV. Claim 13, drawn to a method for assessing the tumor burden of a subject, classified in class 436, subclass 64.
- V. Claims 14-18, drawn to a method of identifying a gene product as a target for a cancer therapeutic, classified in class 435, subclass 7.1.
- VI. Claims 19-22, drawn to a method for identifying agents that decrease biological activity of a gene product, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different processes, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions

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for the following reasons: Groups I-VI are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Group I requires the probe binding level comparison for colon cancer detection which is not required by any other Group. Group II requires comparison of gene product expression levels which differs from the other Groups. Group III requires introducing an antisense polynucleotide to inhibit expression of a gene product which is not required by any other Group. Group IV requires assessing tumor burden which is not required by any other Group. Group V requires identifying a target for a cancer therapeutic which is not required by any other Group. Group VI requires identifying agents that decrease biological activity of a gene product which is not required by any other Group. These distinct methods are often separately characterized and published in literature and would add undue search burden if they were all examined together. Thus, they are considered distinct invention types for restriction purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

February 6, 2006



Carolyn Smith
Examiner
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